REMARKS

Reconsideration of the application is respectfully requested.

I. Status of the Claims

Claims 1 - 6 are currently pending, with claim 7 having been previously canceled

With this Preliminary Amendment, claims 4 - 6 are canceled without prejudice or disclaimer, claim 1 is amended, and new claims 8 and 9 are added. No new matter is introduced. Support for the amendments may be found, for example, with reference to Applicants' specification at page 11, line 20 through page 18, line 5.

II. Rejections under 35 U.S.C. §§ 102, 103

Claims 1-6 were rejected under 35 U.S.C §102(a) as being anticipated by, or in the alternative, rejected under 35 U.S.C §103(a) as being unpatentable over Brugger et al. (U.S. Patent No. 6,554,789, herein "Brugger"). As claims 4 - 6 are canceled without prejudice or disclaimer, Applicants respectfully submit that the rejections as to claims 4 - 6 are moot. Applicants amend claim 1 to further clarify the nature of their invention, and respectfully traverse the rejections of claim 1 - 3 based on Brugger.

In amended independent claim 1, Applicants claim:

1.A blood purification device comprising:

a blood circuit having an arterial blood circuit and a venous blood circuit;

a blood pump disposed in said arterial blood circuit;

a blood purifier connected to the blood circuit between said arterial blood circuit and said venous blood circuit, and configured to purify blood flowing in said blood circuit;

a first measuring unit disposed in said arterial blood circuit and configured to measure a blood concentration of said arterial blood circuit;

a second measuring unit disposed in said venous blood circuit and configured to measure a blood concentration of said venous blood circuit;

a calculating unit configured to calculate a first measurement value and a first theoretical value, said first measurement value referring to a ratio of said blood concentrations measured by said first measuring unit and said second measuring unit, and said first theoretical value referring to a blood concentration ratio obtained by at least one formula based on parameters including a preset blood flow rate of said blood pump and a preset blood purifying rate of said blood purifier;

an evaluation unit configured to evaluate whether a difference between said first measurement value and said first theoretical value is larger than a predetermined acceptable ratio difference; and

a reporting unit configured to report when the difference between said first measurement value and said first theoretical value is larger than the predetermined acceptable ratio difference, wherein when the difference between said first measurement value and said first theoretical value is larger than the predetermined acceptable ratio difference, the reporting unit reports a trouble condition for at least one of said blood pump and said blood purifier.

Brugger discloses a layered fluid circuit for purifying blood (see, e.g., abstract and Col. 9: 24 - Col. 10: 24 of Brugger). The device of Brugger includes a blood pump and blood purifier (see, e.g., Col. 5: 58 - 65), and upstream and downstream hematocrit sensors for sensing pre- and post-treatment blood concentrations (see, e.g., Col. 24: 8 - 34). Brugger teaches a device that periodically measures the difference between pre- and post-treatment hematocrit levels, and determines a fluid reduction ratio based on a current blood flow rate and the measured difference (see, e.g., Col 24: 21 - 34). When the determined fluid reduction ratio differs from a desired ratio, Brugger's device adjusts a flow restrictor to eliminate the difference.

In amended independent claim 1, Applicants claim a device that measures pre- and post-treatment blood concentrations to perform a very distinct function from the flow rate control function performed by the device of Brugger. Specifically, Applicants' claimed device includes a calculating unit, an evaluation unit and a reporting unit configured to perform the following functions. The calculating unit calculates a first measurement value that is represented by a ratio of the blood concentrations measured by first and second measuring units, and calculates a first theoretical value for this ratio based on a current flow rate of the blood pump and a current purifying rate of the blood purifier. The evaluation unit then evaluates whether the difference between the measured ratio of blood concentrations and theoretical ratio of blood concentrations is larger than a predetermined acceptable difference. In the event that the measured difference exceeds the acceptable difference, the reporting unit reports a trouble condition identifying that at least one of the blood pump and the blood purifier is malfunctioning.

Thus, and in sharp contrast to the device disclosed by Brugger, the invention claimed by Applicants is directed to detecting and reporting a trouble condition indicating that at least one of the blood pump or blood purifier is malfunctioning at a predetermined performance rate, rather that providing a mechanism like Brugger for adjusting a flow rate to achieve a desired fluid removal rate. While Brugger's device provides for detecting and reporting an unsafe operating condition (see, e.g., Col. 31: 9 - 15), Brugger nowhere describes or otherwise suggests Applicants' claimed mechanisms for detecting and reporting a malfunction of the blood pump or blood purifier. Applicants' claimed mechanisms provide the advantage of simplifying over prior art systems requiring, for example, additional pressure sensors to detect a degradation in the performance of one or more of the blood pump and blood purifier.

Accordingly, Applicants respectfully submit that Applicants' purification device as claimed in amended independent claim 1 is neither anticipated nor made obvious by Brugger, and stands in condition for allowance. As claims 2 and 3 depend from allowable independent claim 1, Applicants submit that claims 2 and 3 are also allowable for at least this reason.

For the above-argued reasons, Applicants respectfully request that the rejections of claims 1-6 under 35 U.S.C §102(a), or alternatively under 35 U.S.C §103(a), be withdrawn.

II. New Claims

Applicants add new claims 8 and 9. New claim 9 is directed to a method for monitoring for a trouble condition associated with a blood purification device, and comprises steps that essentially parallel the device claim elements of amended claim 1. Accordingly, Applicants submit that new claim 9 is also allowable for at least the reasons argued above in reference to amended independent claim 1.

New claim 8 depends from allowable independent claim 1. For at least this reason, Applicants respectfully submit that new claim 8 is allowable. In addition, Applicants submit that new claim 8 is allowable on additional grounds. New claim 8 claims:

> **8.** The blood purification device of claim 1, wherein:
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> said blood pump is further configured to adjust the preset blood flow rate to an adjusted blood flow rate;
>
> said calculation unit is further configured to calculate a second measurement value and a second theoretical value, the measurement value referring to a ratio of said blood concentrations measured by said first measuring unit and said second measuring unit while said blood pump is operated at said adjusted blood flow rate and said blood purifier is operated at said preset blood purifying rate, and the theoretical value referring to a blood concentration ratio obtained by at least one

formula based on parameters including said adjusted blood flow rate of said blood pump and said preset blood purifying rate of said blood purifier;

said evaluation unit is further configured to evaluate whether said difference between said first measurement value and said first theoretical value is approximately equal to a difference between said second measurement value and said second theoretical value; and

said reporting unit is further configured to report the trouble condition for said blood purifier when said difference between said first measurement value and said first theoretical value is approximately equal to said difference between said second measurement value and said second theoretical value, and to report the trouble condition for said blood pump when said difference between said first measurement value and said first theoretical value is not approximately equal to said difference between said second measurement value and said second theoretical value.

New claim 8 claims the device of amended independent claim 1, in which the blood pump is further configured to adjust the preset blood flow rate, and the calculation unit is further configured a second measurement value and a second theoretical value based on the adjusted blood flow rate. The evaluation unit is further configured to determine whether the difference between the first measurement and theoretical values is approximately equal to the difference between the second measurement and theoretical values, and the reporting unit is further configured to report a trouble condition for the blood purifier when the differences are approximately equal and to report a trouble condition for the blood pump when the differences are not approximately equal. In other words, the blood purification device as claimed in claim 8 is further able to isolate a detected trouble condition as being associated with either the blood pump or the blood purifier. Applicants respectfully submit that these additional features of new claim 8 are neither taught nor suggested by Brugger, and that new claim 8 is allowable for this additional reason.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

The Examiner is respectfully requested to contact the undersigned at the telephone number indicated below if the Examiner believes any issue can be resolved through either a Supplemental Response or an Examiner's Amendment.

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Respectfully submitted,

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